UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

JUDITH GODINEZ, Individually and on Behalf of All Others Similarly Situated, Plaintiffs, v. ALERE INC., *et al.*, Defendants.	Civil Action No. 1:16-cv-10766-PBS

REPLY MEMORANDUM IN FURTHER SUPPORT OF DEFENDANTS' MOTION TO DISMISS THE SUPPLEMENTAL AND AMENDED CONSOLIDATED CLASS ACTION COMPLAINT

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Defendants Alere Inc. ("Alere" or the "Company"), Namal Nawana, James F. Hinrichs, and Carla R. Flakne (the "Individual Defendants" or, together with Alere, "Defendants") respectfully submit this reply memorandum of law in further support of their motion to dismiss the Supplemental and Amended Consolidated Class Action Complaint (the "Complaint").

PRELIMINARY STATEMENT

Plaintiffs' highly rhetorical brief cannot obscure the fundamental defects identified in Defendants' motion to dismiss that pervade the Complaint. At root, the problem with the Complaint is that it fails to allege with the particularity demanded by First Circuit law and the PSLRA that Defendants acted with scienter. The Complaint pleads no facts indicating that Defendants had actual knowledge or were reckless in not knowing of the issues concerning revenue recognition in Africa and China, the handful of billing errors made over a five-year period by the Arriva subsidiary, or the alleged billing misconduct at a Texas toxicology lab that accounted for significantly less than 1% of Alere's revenue. And Plaintiffs offer no answer to Defendants' demonstration that the amounts of revenue implicated by each of these problems was entirely immaterial to the Company's financial performance, so that it would have been irrational for Defendants to have permitted such activities.

Nor has the Complaint identified facts showing that Defendants knew that the Company's costly 20-month effort to correct technical problems affecting its INRatio test strips would ultimately be rejected by the FDA. Here too, the Complaint cannot account for the irrationality of devoting significant resources to a program Defendants supposedly knew was doomed from the start.

Significantly, no confidential witness cited in the Complaint ascribes relevant knowledge to any of the Individual Defendants. And Defendant Carla Flakne, the Company's

Chief Accounting Officer, to whom Plaintiffs make a sole innocuous reference on the first page of their brief, is never again mentioned in the 39 pages that follow.

Plaintiffs adopt three basic strategies to overcome or obscure these deficiencies, but none holds water.

First, Plaintiffs place heavy reliance on assertions made by Abbott Laboratories ("Abbott") in its litigations against Alere to terminate the Merger Agreement. On April 14, 2017, however, Abbott voluntarily dismissed all of its claims *with prejudice* and announced that it was going to consummate its agreement to acquire Alere for $51 per share, a modest reduction from the original transaction price and still a massive premium to the unaffected price. Abbott's disavowal of its allegations against Alere, which comes after Abbott received extensive litigation discovery (including through Alere's voluminous document productions and by taking fourteen depositions of fact witnesses) and only days before the trial scheduled in Delaware Chancery Court, is a complete repudiation of Plaintiffs' theories of liability here. At a minimum, Plaintiffs can no longer argue that those allegations support their fraud claims. But even before Abbott's litigations were withdrawn, Abbott's allegations never supported Plaintiffs' theory of fraud. The essence of Abbott's claim was that there were material adverse events at Alere postdating the January 2016 merger agreement that *neither Abbott nor Alere knew or could have known about* at the time the deal was signed. Equally important, Abbott's claims of nondisclosure were based on alleged breaches of a *private contractual undertaking* to provide access to nonpublic information as reasonably requested by Abbott, during the period *after* the Merger Agreement had been signed. The whole point of affording Abbott this limited, post-signing access right—governed by strict nondisclosure rules—was to give Abbott access to granular information to which the public markets were not entitled. Plaintiffs cannot equate a contractual obligation to

disclose nonpublic information with the duties to disclose public information in SEC filings.

Second, Plaintiffs strain mightily to ascribe an economic motive for Messrs. Nawana and Hinrichs to have made misstatements. But those assertions are flatly inconsistent with undisputed facts (including Mr. Hinrichs's purchase of $1 million worth of Alere shares with his own money). Moreover, even strong motive allegations (missing here) are no substitute under First Circuit law for well-pleaded factual allegations of *knowledge*.

Third, Plaintiffs urge that the Court should look at their allegations as a whole and argue that even if each of the specific categories of misstatement at issue here are not material or made with scienter, all involve internal control weaknesses. But Plaintiffs paint with too broad a brush; the only internal control weaknesses relate to revenue recognition errors, not to any of Plaintiffs' other allegations on completely unrelated subjects. In any event, combining several inactionable claims in a single complaint does not transform the complaint into a viable securities fraud lawsuit. Zero plus zero plus zero equals zero.

ARGUMENT

I. Allegations Copied and Pasted from the Now-Abandoned Abbott Litigation Do Not Support Scienter or Securities Fraud.

Plaintiffs' strategy in their Complaint and opposition brief has been to piggyback on allegations made by Abbott in its dispute with Alere over the Merger Agreement.[1] However, on the eve of trial, after months of document discovery and depositions, Abbott dismissed all of its claims against Alere with prejudice and has agreed to consummate the Merger Agreement for $51 per share—a modest reduction from the original acquisition price.[2] Abbott has thus

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[1] *See, e.g.*, ¶¶ 5, 8, 119, 124−127, 131−132, 140−144, 170-171,233, 240−243, 247, 256; Opp'n at 19−21; 30 n.14; 31 n.15; 37−39; Opp'n Ex. E.

[2] The merger consideration to be paid by Abbott under the settlement is $51 per share, the mean of the $49 to $53 per share that Abbott indicated it would be willing to pay for Alere in December 2015. (*See* Ex. 23.) *See*

decisively repudiated, and dismissed with prejudice, all of the claims and arguments—concerning revenue recognition, internal controls, Arriva, INRatio, the FCPA and so on—with which Class Plaintiffs so eagerly associated themselves by repeatedly citing the allegations made by Abbott. (Exs. 22 & 23.) Abbott's actions show why the law is that plaintiffs cannot rely on allegations from an unadjudicated complaint to sustain their claims. *See Aronson* v. *Advanced Cell Tech., Inc.*, 972 F. Supp. 2d 123, 136 (D. Mass. 2013) (observing that "[a] pleading may not adopt other pleadings from a wholly separate action"). That conclusion is even more compelling when the lawsuit on which plaintiffs placed such heavy reliance is voluntarily dismissed with prejudice. *See, e.g.*, *RSM Product. Corp.* v. *Fridman*, 643 F. Supp. 2d 382, 403 (S.D.N.Y. 2009) (striking allegations based on "complaints filed in actions that were never resolved on the merits" such as "complaints in other actions that have been dismissed, settled, or otherwise not resolved"). All of Plaintiffs' allegations drawn from Abbott's litigation filings therefore should be disregarded.[3]

Abbott's claims never supported Plaintiffs' allegations anyway. Abbott never alleged that Alere committed fraud by failing to disclose material information—indeed, its theory was that the events that arose after the signing of the Merger Agreement were equally unknown to Abbott *and Alere*.[4] Nor did Abbott's allegations regarding Alere's contractual

Brennan v. *Zafgen, Inc.*, --- F.3d ---, 2017 WL 1291194 at *1 (1st Cir. April 7, 2017) (noting that the court will consider SEC filings attached as exhibits accompanying the motion to dismiss).

3 In light of the voluntary dismissal of the Abbott litigations, Plaintiffs' contention that those litigations constitute new, actionable developments must also fail. (*See* Opp'n at 38.) Furthermore, the risk that Abbott would sue to terminate the Merger Agreement was disclosed, known, and has since materialized and disappeared. The materialization of a disclosed risk cannot support a claim of securities fraud. *See, e.g.*, *In re Boston Sci. Corp. Sec. Litig.*, 490 F. Supp. 2d 142, 154 (D. Mass. 2007), *rev'd and remanded on other grounds sub nom.*, *Mississippi Pub. Emps Ret. Sys.* v. *Boston Sci. Corp.*, 523 F.3d 75 (1st Cir. 2008).

4 (*See, e.g.*, Ex. 24 ¶ 12 ("Alere of course never disclosed [to Abbott facts concerning the withdrawal of INRatio from the market], *presumably because it did not know* . . . .") (emphasis added); Ex. 25 ¶ 22, (basing request for declaratory judgment that would allow Abbott to terminate the merger on list of "events—all of which occurred after Alere signed the Merger Agreement . . . .").)

disclosure obligations arising out of the Merger Agreement support Plaintiffs' claims.[5] Whatever contractual obligations Alere may have to disclose information to Abbott after execution of the Merger Agreement have no bearing on what Alere was required to disclose in its public SEC filings, because the purpose of those contractual provisions is to provide Abbott with access to a greater wealth of information than Alere must disclose publicly.

II. Plaintiffs Do Not Plead Securities Fraud Related to Revenue Recognition.

A. Plaintiffs' Allegations Do Not Raise a Strong Inference of Scienter.

Plaintiffs fail to address the numerous undisputed facts that undermine any inference of scienter with respect to revenue recognition. Plaintiffs do not dispute that the transactions in Africa and China do *not* involve any fictitious sales or phantom revenue and that the adjustments to Alere's financial statements merely shift *real* revenue from *genuine* transactions from earlier quarters to later quarters. Nor do Plaintiffs challenge Alere's painstaking public explanation of the source of the errors in question, all of which were attributable to good faith mistakes made by local financial staff, not to fraud.[6]

Plaintiffs also do not dispute that the dollar amounts of the adjustments were not material to Alere's gross profits and net revenues, further undercutting any inference of scienter. *See In re ARIAD Pharm., Inc. Sec. Litig.*, 842 F.3d 744, 750 (1st Cir. 2016). When "the overall effect of the improper accounting on the company's financial result was modest, an attribution of scienter is less plausible." *Thomas* v. *Shiloh Indus., Inc.*, No. 15-cv-7449, 2017 WL 1102664, at *4 (S.D.N.Y. Mar. 23, 2017). Finally, Plaintiffs do not dispute that Alere's disclosure that it would delay its 2015 Form 10-K was made promptly after senior management, in February 2016,

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[5] (*See* Ex. 26 ¶ 39 (alleging that Alere's refusal to produce documents to Abbott was a breach of Merger Agreement).)

[6] The revenue recognition errors disclosed by Alere in February 2016 arose in connection with foreign sales contracts with idiosyncratic terms that required individualized and fact-intensive application of the revenue recognition rules. (*See* Defs. Br. at 13–15.)

learned of the potential errors with respect to sales in Africa and China. *In re Genzyme Corp. Sec. Litig.*, 754 F.3d 31, 42 (1st Cir. 2014); *see also Brennan* v. *Zafgen, Inc.*, --- F.3d ---, 2017 WL 1291194, at *8 (1st Cir. April 7, 2017) ("We also note that [the Company's] own disclosures both before and during the class period weaken the complaint's scienter showing."). Taken together, these facts—all unanswered by Plaintiffs—establish that the more plausible inference to be drawn is that Alere's revenue recognition adjustments were the result of unintentional errors, contemporaneously unknown to Defendants.

None of the arguments Plaintiffs have advanced supports any competing—let alone strong—inference of fraud. First, Plaintiffs posit that scienter may be assumed when GAAP violations are "simple and obvious" (Opp'n at 26), but even if these errors should have been "obvious" to local accountants overseeing Alere's revenue recognition in Africa and China, that does not mean that the Company's senior management in Massachusetts would have known about them, and Plaintiffs do not allege any facts showing that they did.

Second, in the case on which Plaintiffs principally rely, this Court expressly recognized that "'defendant's failure to recognize revenue in accordance with GAAP does not, by itself, suffice to *establish* scienter'" without "other circumstances indicative of fraudulent intent." *In re Raytheon Sec. Litig.*, 157 F. Supp. 2d 131 (D. Mass. 2011) (Saris, J.) (quoting *Chalverus* v. *Pegasystems, Inc.*, 59 F. Supp. 2d 226, 233 (D. Mass. 1999) (emphasis in *In re Raytheon*)); *accord Greebel* v. *FTP Software, Inc.*, 194 F.3d 185, 203–04 (1st Cir. 1999) (no reasonable inference of scienter raised by the plaintiff's allegation of GAAP violations). No such "other circumstances" have been adequately pleaded here. (*See also* Defs. Br. at 15 n.62 (distinguishing *In re Raytheon*).)

Third, Plaintiffs' opposition relies heavily on the false premise that scienter is

established whenever a company discloses a weakness in its internal controls—a rule that would subject companies in this District to automatic securities fraud complaints when making such a disclosure. But, whenever a company restates its financials due to a GAAP error, it invariably must also disclose inadequate internal controls. *See Karpov* v. *Insight Enters., Inc.*, No. CV 09-856-PHX-SRB, 2010 WL 2105448, at *10 (D. Ariz. Apr. 30, 2010); *accord Roth* v. *OfficeMax, Inc.*, 527 F. Supp. 2d 791, 797 (N.D. Ill. 2007). Thus, for all the same reasons that a restatement of financials or a violation of GAAP does not suffice to plead fraud, an accompanying disclosure of weakness in internal controls—without more—also cannot establish scienter. *See In re Turquoise Hill Res. Ltd. Sec. Litig.*, No. 13 Civ. 8846, 2014 WL 7176187, at *8 (S.D.N.Y. Dec. 16, 2014) (holding that the "accounting controls were an after-the-fact explanation for why the error had occurred, not a red flag before it was discovered").[7]

Fourth, Plaintiffs make much of the fact that Alere had—prior to the beginning of the class period—disclosed an unrelated internal control weakness relating to the accounting for deferred tax assets and income taxes (both generally and in connection with two divestitures). (¶ 229.) But Plaintiffs do not identify any relationship between errors in the calculation of corporate taxes and errors in revenue recognition for sales in Africa and China.[8] *See Karpov*, 2010 WL 2105448, at *10 (holding that plaintiffs must allege "specific details regarding how or under what circumstances [the] Defendants were aware of the weakness in internal controls or

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[7] The same is true of Plaintiffs' claims relating to the Company's SOX certifications, which are inactionable absent particularized allegations that Defendants knew, or were highly reckless in failing to know, that revenue was being recognized early. *Id.* at *7; *see also Zucco Partners, LLC* v. *Digimarc Corp.*, 552 F.3d 981, 1004 (9th Cir. 2009) (noting that circuit courts that have ruled on this issue have "unanimously agreed that allowing [SOX] certifications to create an inference of scienter" would "eviscerate the pleading requirements for scienter set forth in the PSLRA" (alterations in original accepted) (citation and internal quotation marks omitted) (collecting cases)).

[8] *Varghese* v. *China Shenhuo Pharmaceutical Holdings, Inc.*, 672 F. Supp. 2d 596 (S.D.N.Y. 2009), on which Plaintiffs rely, is not to the contrary. In *Varghese*, the multiple general "internal controls" issues were all related to the only type of accounting error alleged in the complaint. *Id.* at 602–03.

the connection between that weakness and trade credit accounting").

Fifth, Plaintiffs do not dispute that none of their confidential witnesses had direct communications with any Individual Defendant. Plaintiffs instead rely on vague, conclusory assertions, unanchored by reference to any specific facts, that "knowledge of inadequate financial controls was widespread at Alere." (Opp'n at 29.) But Plaintiffs' confidential witnesses do not claim that they themselves knew that revenue was being recognized prematurely, let alone that Defendants knew it.[9]

Sixth, Plaintiffs argue that Defendants Nawana's and Hinrichs's general familiarity with Alere's systems and processes and "unfettered access" to information supports an inference of scienter. (Opp'n at 28, 30.) But such overall familiarity and information access proves too much; this could be said of the CEO and CFO of *every* public company. *See Local No. 8 IBEW Ret. Plan* v. *Vertex Pharm., Inc.*, 838 F.3d 76, 82–83 (1st Cir. 2016).

Finally, Plaintiffs seek to draw an inference of scienter from the fact that there was a time lag of only weeks between the execution of the Merger Agreement with Abbott and Alere's disclosure of the potential revenue recognition issues. (Opp'n at 39.) The Merger Agreement stated that management has not "identified or been made aware" of any deficiencies in internal controls over revenue recognition. When management thereafter learned of the issue, the Company promptly disclosed it on February 26 and announced a delay in filing its 2016 Form 10-K. There is nothing inconsistent between the representation of the Company's state of knowledge at the time of the Merger Agreement and its prompt subsequent disclosures when

[9] For this reason, Plaintiffs' reliance on *In re Cabletron Systems, Inc.*, 311 F.3d 11 (1st Cir. 2002) and *Collier* v. *ModusLink Global Solutions, Inc.*, 9 F. Supp. 3d 61 (D. Mass. 2014) is misplaced. In *Cabletron*, multiple witnesses with "personal knowledge" of the "precise means through which [the alleged fraud] occurred" offered "specific descriptions" of those actions. 311 F.3d at 30. In *Collier*, the witness statements directly tied the defendants to specific wrongful actions. 9 F. Supp. 3d at 71–72. Neither is analogous to the statements offered by Plaintiffs, which lack any such connection or particularity. (*See* Defs. Br. at 16−17.)

new facts became available. And the expeditiousness of its disclosure is flatly inconsistent with scienter or any attempt to conceal the truth.[10]

B. The Adjustments to Alere's Financial Statements Were Immaterial as a Matter of Law.

Plaintiffs do not contest that Alere's revenue recognition adjustments had the effect of shifting about $21 million in real revenue from 2013–14 to 2015–16. Plaintiffs also do not dispute that Alere's net revenue and gross margins were revised by 0.5% or less for 2013, 2014, and the first 9 months of 2015—percentage changes that are immaterial as a matter of law under the First Circuit's controlling decision in *Glassman* v. *Computervision Corp.*, 90 F.3d 617, 633 n.26 (1st Cir. 1996) (noting that a 9% discrepancy was insufficient to support a claim of materiality). And Plaintiffs do not challenge the conclusion of Alere's independent auditors that these revisions were not material, individually or in the aggregate. (*See* Defs. Br. at 6.)

Instead, Plaintiffs retreat to the contention that only one financial metric, Alere's "Income (Loss) from Continuing Operations" for the first 9 months of 2015, should be used to evaluate materiality. But there is no basis, in law or the accounting literature, for looking at any single line item on a company's financial statements in isolation and out of context. As explained in Defendants' opening brief, Alere consistently reports a relatively modest figure for this metric because it nets out large amortization and interest expenses. (Defs. Br. at 22 & n.85.) Thus, even a small *dollar* revision to this line item can effect an enormous *percentage* change

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[10] By contrast, cases cited by Plaintiffs involve inconsistent statements or outright contradictions. *See Shaw* v. *Digital Equip. Corp.*, 82 F.3d 1194, 1225 (1st Cir. 1996) (statement about additional required restructuring efforts followed shortly after a prior statement that no additional restructuring efforts would be needed); *Gerber* v. *Bowditch*, No. 05-10782-DPW, 2006 WL 1284232, at *11−12 (D. Mass. May 8, 2006) (defendants omitted company's eligibility for revenue increase under federal program in tender offer to limited partners, then applied for program weeks after end of tender period). Two other cases cited by Plaintiffs are likewise inapposite because they involve third-parties who discover an alleged fraud after being granted access to the defendants' financial records. *See In re Salix Pharm., Ltd.*, No. 14-cv-8925 (KMW), 2016 WL 1629341, at *14 (S.D.N.Y. Apr. 22, 2016) (multiple bidders discovered errors in potential target's inventory levels); *In re Bear Stearns Cos. Inc. Sec. Derivative & ERISA Litig.*, 763 F. Supp. 2d 423, 517 (S.D.N.Y. 2016) (acquirer discovered overvaluation of target company's assets).

from quarter to quarter. (*Id.*); *see also Shiloh Indus., Inc.,* 2017 WL 1102664, at *4 (adopting defendant's argument that even though the company's net income was overstated by approximately 50% and 13% in two consecutive quarters, the discrepancy had an "exaggerated effect" on net income, and the appropriate measure was the impact on cost of sales, for which there was a minimal change of 0.7% and 0.4% over the same two quarters).[11] Plaintiffs assert that income is the metric that investors care about, but that generalization is no substitute for a review of the actual financial information about the particular company at issue.[12]

Plaintiffs also argue that materiality is a mixed question of law and fact that courts find inappropriate for resolution at the motion to dismiss stage. (Opp'n at 22.) In fact, courts routinely do dismiss complaints at the motion to dismiss stage for failure to adequately plead materiality. (*See* Defs. Br. at 21.)

Finally, Plaintiffs assert that Alere conceded the materiality of its revenue recognition errors in its July 14, 2016 press release. This is misleading, to say the least. The press release disclosed that the adjustments resulting from Alere's premature recognition of this real revenue were not material to any of its previously issued financial statements from 2013 and 2014, but that the cumulative effect of recognizing this revenue in the correct time period would be material to its 2015 financial statements. But, as plaintiffs surely understand, the cumulative effect of shifting this revenue from 2013 and 2014 to 2015 was that net revenue *increased* by

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[11] Plaintiffs argue that materiality is established by the decline in Alere's stock price following the February 26, 2016 disclosure that there would be a delay in filing the Form 10-K. (Opp'n at 25.) But that disclosure did not quantify the amount of the errors. Once Alere did quantify the amount of the errors in its August 8, 2016 10-K, Alere's stock price went up.

[12] *Crowell* v. *Ionics, Inc.*, 343 F. Supp. 2d 1 (D. Mass. 2004), on which Plaintiffs rely (Opp'n at 24–25), does not support the proposition that the court must look to income instead of revenue in determining the materiality of a downward revision. *Crowell* merely stated (in dictum) that "most" investors care about income. 343 F. Supp. 2d at 18.

Plaintiffs also incorrectly suggest that Defendants have ignored controlling law in *Ganino* v. *Citizens Utilities Co.*, 228 F.3d 154, 163 (2d Cir. 2000). (Opp'n at 25–26.) *Ganino* is a Second Circuit decision, and merely states that materiality "necessarily depends on all relevant circumstances of the case." *Id.* at 162.

$12 million for the fourth quarter of 2015. (*See* Defs. Br. at 6−7.) In any event, not every GAAP violation is material. *See Takara Trust* v. *Molex Inc.*, 429 F. Supp. 2d 960, 978 (N.D. Ill. 2006) (noting that "restating a company's earnings does not make the original misstatement material *per se*"); *see also Glassman* v. *Computervision Corp.*, 90 F.3d 617, 633 n.26 (1st Cir. 1996).

III. Plaintiffs Do Not Plead an Actionable Misstatement or Omission Related to Arriva.

Plaintiffs do not dispute that the number of claims that Alere's subsidiary Arriva billed to Medicare erroneously on behalf of deceased patents accounted for a minuscule 0.003% of the 5.7 million total claims that were submitted during the relevant five-year period. This fact alone undermines any inference that Defendants knew of such minor errors or intentionally concealed them.

Plaintiffs argue that the Individual Defendants should have known about these billing errors because even a small number of claims for deceased beneficiaries can result in the loss of Medicare billing privileges. But it is implausible to infer that Defendants would intentionally bill for 211 deceased patients to achieve an inconsequential increase in revenue, at the risk of regulatory cancellation of their Medicare billing privileges. Even if the consequences of erroneously submitting a small number of claims for deceased beneficiaries are potentially draconian, it does not follow that the CEO and CFO of a large enterprise with multiple lines of business and thousands of employees would be personally involved in the billing process of every business unit, and Plaintiffs allege no such facts.

In addition, as Defendants pointed out in their opening brief, Plaintiffs do not support with any factual allegations their conclusory assertion that Arriva lacked sufficient internal controls to prevent such errors; indeed, the extremely small number of errors out of millions of transactions suggests that Arriva's internal controls were strong, not weak.

Moreover, because Plaintiffs fail to show that the CID had anything to do with claims submitted for deceased beneficiaries, Plaintiffs also have not shown that the CID put Defendants on notice of the billing issues. (Defs. Br. 36–37.)

IV. Plaintiffs Do Not Plead an Actionable Misstatement or Omission Related to INRatio.

Plaintiffs' claim regarding Alere's July 2016 recall of INRatio is impermissible "fraud by hindsight." But as the First Circuit recently observed, "'fraud by hindsight' does not satisfy the pleading requirements in a securities fraud case." *Ganem* v. *Invivo Therapeutics Holdings Corp.*, 845 F.3d 447, 457 (1st Cir. 2017).

As demonstrated in Defendants' opening brief, Defendants were under no obligation to assume that the costly remediation efforts undertaken by Alere would ultimately fail or to initiate a recall of the INRatio product line any earlier than July 2016. (*See* Defs. Br. 23–26.) Plaintiffs do not meaningfully respond to these arguments, nor do they point to any facts that would establish that the Individual Defendants actually believed that a loss was reasonably probable prior to July 2016. *See Fire and Police Pension Ass'n of Colorado* v. *Abiomed, Inc.*, 778 F.3d 228, 244–45 (1st Cir. 2015) (noting that evidence that the company was involved "in finding a solution amenable to the FDA while meeting its need to market its products" undercut an inference of scienter).

Instead, Plaintiffs argue that because Alere ultimately *did* recall the INRatio products and, in August 2016, recorded a charge for the year ending in 2015, Defendants had to know that information much earlier. Specifically, Plaintiffs claim that "the circumstances giving rise to the voluntary withdrawal . . . existed as of December 31, 2015" and that Alere should have recalled the INRatio products by that date. (Opp'n at 34.) Plaintiffs' sole basis for this bold claim is that the Company recorded INRatio recall charges in the fourth quarter of 2015. (*Id.*)

But, as noted in Plaintiffs' own pleading, Alere did not issue its 2015 10-K until August 2016, roughly five months late. Its determination to record such charges was not made until August 2016, when the recall actually occurred.[13] Thus, Plaintiffs cannot establish a claim of securities fraud arising out of Defendants' failure to disclose a loss contingency pursuant to ASC 450 any earlier than Alere did. *See Fait* v. *Regions Fin. Corp.*, 655 F.3d 105, 113 (2d Cir. 2011); *In re Hutchinson Tech. Inc. Sec. Litig.*, 502 F. Supp. 2d 884, 895 (D. Minn. 2007), *aff'd*, 536 F.3d 952 (8th Cir. 2008).

Plaintiffs' other scienter arguments are similarly unavailing. Plaintiffs assert that scienter may be inferred by the facts that (i) INRatio products had previously been subject to a partial recall and correction in 2014, (ii) a large number of complaints were filed with the FDA regarding the INRatio products, and (iii) INRatio was an important product for Alere. But it is undisputed that, rather than hiding anything, Alere made extensive public disclosures regarding its difficulties with the INRatio products throughout the class period. (*See* Defs. Br. 23–24.) Plaintiffs also suggest that Defendants' attempts to resolve the issues with the INRatio products were motivated by a desire to forestall potential product liability lawsuits, but that is merely speculation unsupported by any particularized allegations. The more plausible inference is that Alere wanted to fix the product because it believed it was a useful product for its customers and wanted to continue to sell it to them.

[13] Alere's determination is consistent with the relevant accounting principles for recognizing subsequent events, pursuant to which losses are sometimes recognized in prior quarters even when the final outcome was not—and could not have been—certain at the time. For instance, "a loss on an uncollectible trade account receivable as a result of a customer's deteriorating financial condition leading to bankruptcy after the balance sheet date but before the financial statements are issued or are available to be issued ordinarily will be indicative of conditions existing at the balance sheet date." FASB 855-10-55-1 (Fin. Accounting Found. 2016). That is precisely what happened here: as Alere disclosed throughout 2014 and 2015, its INRatio products were subject to various concerns which it had reported to the FDA. Its withdrawal of those products from the market in 2016 was the culmination of an unsuccessful process to attempt to fix those issues. But applying the accounting charge in 2015 does not establish either that withdrawal was a foregone conclusion at that time or that Defendants knew in 2015 that the proposed improvements would be rejected by the FDA in July 2016.

Next, Plaintiffs' allegations of scienter are further undermined by the immateriality of the INRatio recall to Alere's overall financial performance. Plaintiffs claim that the recall was material because it "caus[ed] gross profits to decrease by $99.7 million, or 8%, for 2015, from $1.21 billion for 2014." (Opp'n at 25.) In fact, the disclosure quoted states that only $39.1 million of the decrease in gross profits (3.2%) was attributable to the recall. The remainder of the decline was due to various unrelated issues, including "a challenging foreign exchange environment in international markets." (Opp'n Ex. D.)

Finally, Plaintiffs claim that "the seniority" of confidential witnesses provides circumstantial evidence of scienter. Leaving aside that a Customer Service V.P. and a Quality Assurance Associate are not senior decision makers who had access to information about the likely success of the efforts to fix the problem with the INRatio product, the bigger problem is that, as explained in Defendants' opening brief, irrespective of their seniority, neither of the confidential witnesses was in a position to know what the Individual Defendants knew or believed regarding INRatio, or whether a product recall was appropriate or necessary, or whether it was appropriate to establish a reserve under the accounting rules. Their statements therefore do not support Plaintiffs' theory of scienter.

V. Plaintiffs Do Not Plead an Actionable Misstatement or Omission Related to Compliance with the FCPA.

As discussed in Defendants' opening brief, the mere fact that Alere has received a subpoena from the DOJ regarding FCPA compliance does not suggest that any wrongdoing has actually occurred or that Defendants had any knowledge of any wrongdoing. (*See* Defs. Br. 33 & n.116 (collecting cases).) Plaintiffs do not argue otherwise. Rather, Plaintiffs respond with a generalized assertion that Alere did not maintain an adequate system of internal controls to prevent an FCPA violation. But the mere fact that Alere received a subpoena from the DOJ

regarding FCPA compliance does not support that conclusory proposition either. Indeed, the DOJ recognizes that "a company's failure to prevent every single violation does not necessarily mean that a particular company's compliance program was not generally effective."[14] Moreover, given that Alere operates in more than 30 foreign countries, including numerous countries in emerging markets, and has over 9,000 employees, even if the DOJ ultimately were to find that Alere violated the FCPA, failure to disclose the facts underlying any such violation would not amount to securities fraud in the absence of any allegations suggesting that the misconduct was material and Defendants knew about it. Plaintiffs make no such allegations.

VI. Plaintiffs Do Not Plead an Actionable Misstatement or Omission Related to Alere's Toxicology Lab.

Plaintiffs do not substantively respond to Defendants' motion to dismiss claims arising out of billing issues at Alere's toxicology lab in Texas. Indeed, Plaintiffs ignore the fact that the single Texas toxicology lab subject to the July 2016 DOJ subpoena accounts for "significantly less than 1% of Alere's total revenues" in the first 9 months of 2015, which negates any inference of scienter. Nor do Plaintiffs meaningfully dispute that the DOJ subpoena issued in July 2016 in no way establishes that any wrongdoing ever actually occurred, let alone that senior management was on notice of it. As for the complaint filed by Horizon Blue Cross and Blue Shield in 2013, which predates Mr. Nawana and Mr. Hinrichs joining the Company, Plaintiffs fail to respond to the showing that it concerned an unrelated subject and was never adjudicated. It fails to support the sufficiency of the fraud claims in this suit. *See Menaldi* v. *Och-Ziff Capital Mgmt. Grp. LLC*, 164 F. Supp. 3d 568, 578 (S.D.N.Y. 2016).

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[14] Criminal Division of the United States Department of Justice and Enforcement Division of the United States Securities and Exchange Commission, *FCPA: A Resource Guide to the U.S. Foreign Corrupt Practices Act* at 56 (Nov. 14, 2012), https://www.justice.gov/sites/default/files/criminal-fraud/legacy/2015/01/16/guide.pdf; *see also id.* ("DOJ and SEC understand that 'no compliance program can ever prevent all criminal activity by a corporation's employees,' and they do not hold companies to a standard of perfection." (quoting U.S. Dep't of Justice, United States Attorneys' Manual § 9-28.800.B)).

VII. Plaintiffs' Allegations Concerning the Individual Defendants' "Motive" Are Neither Sufficient to Plead Scienter Nor Credible.

As explained in Defendants' opening brief, Plaintiffs' allegations of scienter are further undermined by the fact that Messrs. Nawana and Hinrichs increased their stock holdings and options during the putative class period. (*See* Defs. Br. 3, 4–5.) And Hinrichs spent over $1 million of his personal funds to buy shares on the open market during the class period. *See Fire & Police Pension Ass'n of Colorado* v. *Abiomed, Inc.*, 778 F.3d 228, 246 (1st Cir. 2015) ("Here, the trading cited in the complaint was neither unusual nor suspicious. Minogue increased his holdings of Abiomed stock by 9.2% during the Class Period, which negates any inference that he had a motive to artificially inflate Abiomed's stock during that period."); *In re Bristol-Meyers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) ("[T]he Individual Defendants, in almost every instance, *increased* their . . . holdings during the Class Period—a fact wholly inconsistent with fraudulent intent.") (emphasis in original). In their opposition, Plaintiffs argue that Nawana's and Hinrichs's increase in their stock holdings was all part of a purported plan to enrich themselves in an eventual merger.[15] (Opp'n at 17–18.) But the First Circuit has rejected such speculative allegations of supposed motive in favor of a fact-specific inquiry into whether a "strong" inference of scienter could be fairly drawn from a plaintiff's particularized allegations. *See Greebel*, 194 F.3d at 196–97; (*see also* Defs. Br. at 19 n.75 (routine change-in-control payments insufficient to plead scienter).)

The motives Plaintiffs ascribe to Nawana and Hinrichs are not just implausible, but nonsensical. First, for Plaintiffs' theory of scienter to work, Nawana and Hinrichs would have to have had extraordinary clairvoyance: both to predict whether and when a buyer would emerge and that due diligence would not reveal the allegedly concealed problems prior to

[15] Plaintiffs do not make any arguments regarding Individual Defendant Flakne.

acquisition. *See In re Stone & Webster, Inc. Sec. Litig.*, 253 F. Supp. 2d 102, 127–28 (D. Mass. 2003), *rev'd in part on other grounds*, 414 F.3d 187 (1st Cir. 2005) (holding that change-in-control incentives did not suffice to plead scienter because individual defendants could not have plausibly contrived to sell the company at precisely the right time before the alleged fraud was revealed).[16]

Second, it would make no sense for Defendants to make any of the alleged misrepresentations or engage in any of the underlying conduct in order to attract a merger partner. For example, it would be irrational to conceal the inconsequential economic benefits to Alere arising from the mistimed revenue recognition—as stated above, the revisions affected 0.5% or less of Alere's net revenue and gross margin for 2013, 2014 and the first 9 months of 2015—to attract an acquisition offer. That is especially true given that the Company disclosed these errors weeks after signing the Merger Agreement, leading to a legal battle that jeopardized the closing of that very merger, until Abbott reversed course and reaffirmed its commitment to the transaction. (*See* Ex. 23.)

It would be equally irrational to submit 211 bills on behalf of deceased patients out of 5.7 million total claims—less than 0.003% of Arriva's business—in order to invite more attractive merger offers, all while risking draconian regulatory sanctions that could cut off the entire revenue stream from that business segment and thereby again also risk a negative reaction from one's merger partner. Although Abbott has now dismissed its lawsuit and reaffirmed its commitment to the transaction, its previous efforts to terminate the merger by invoking a

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[16] In its opinion, the First Circuit expressly "agree[d] with the district court that [defendants'] change-in-control agreements did not provide a strong motive to engage in fraud." *In re Stone & Webster*, 414 F.3d at 201 n.9. By contrast, the defendants in the cases cited by Plaintiffs stood to gain merely by staying in their positions or meeting profitability thresholds, neither of which depended on the unpredictable involvement of a third-party bidder. *See Collier* v. *ModusLink Glob. Sols., Inc.*, 9 F. Supp. 3d 61, 75 (D. Mass. 2014); *Chalverus* v. *Pegasystems, Inc.*, 59 F. Supp. 2d 226, 236 (D. Mass. 1999).

purported "materially adverse event" attributable to the Arriva situation only highlights how implausible it would have been for Messrs. Nawal and Hinrichs to engage in any of this behavior in the hope that they would personally profit.

VIII. Plaintiffs' Allegations Do Not Improve When Viewed "Holistically."

In their opposition, Plaintiffs exhort the Court to view their allegations of scienter collectively. Such a holistic analysis of Plaintiffs' Complaint does nothing to remedy the deficiencies fatal to the Complaint outlined above and in Defendants' opening brief. *See Thomas* v. *Shiloh Indus., Inc.*, No. 15-cv-7449, 2017 WL 1102664, at *6 (S.D.N.Y. Mar. 23, 2017) ("Several insufficient allegations of recklessness can never add up to a compelling inference of scienter."). Whether considered together or in isolation, Plaintiffs' allegations, even if true, do not establish that any Individual Defendant knew, or should have known, of any alleged misstatement. Nor does any of the alleged indirect evidence of scienter add up. As discussed above, none of Plaintiffs' confidential witnesses interacted with, or had specific knowledge regarding, the Individual Defendants and thus lend no plausibility to Plaintiffs' theory of intent.

Plaintiffs also attempt to paint a picture of a company with a series of deficient internal controls (Opp'n at 1) and argue that this lawyer's *characterization* is an adequate substitute for well-pleaded *facts*. But the only internal controls problem that Alere has identified during the class period relates to revenue recognition. Plaintiffs' other allegations concern completely unrelated miscellaneous issues across Alere's complex business, none of which implicate financial reporting or accounting controls. Nor can it be inferred that the Individual Defendants, who have not been adequately alleged to have known about any of these discrete problems, somehow nevertheless knew that Alere's disclosures were materially misleading.

This is especially true because Alere is regulated by a wide variety of government entities—including CMS, FDA, SEC, and DOJ—and a misstep in one sphere is not correlated

with a misstep in a completely different segment of the business subject to a different regulatory regime. Plaintiffs do not and cannot explain why or how these unrelated issues might interconnect or provide any other reason to credit their conclusory allegations. *See, e.g.*, *Fire & Police Pension Ass'n of Colorado* v. *Abiomed, Inc.*, 778 F.3d 228, 231 (1st Cir. 2015) ("Not all claims of wrongdoing by a company make out a viable claim that the company has committed securities fraud."); *see Coyne* v. *Metabolix, Inc.*, 943 F. Supp. 2d 259, 273 (D. Mass. 2013) (finding that plaintiff failed to plead scienter because "the allegations in the Amended Complaint in this case fall well below this level of specificity, stating only that the Defendants were high-ranking executives and attended unspecified meetings where they discussed unspecified topics.").

CONCLUSION

For the reasons set forth above and in Defendants' moving brief, Defendants respectfully request that the Court dismiss the Complaint with prejudice.

Dated: May 1, 2017

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document, filed through the CM/ECF System, will be served electronically on the registered participants as identified on the Notice of Electronic Filing ("NEF") and paper copies will be sent to those indicated as nonregistered participants via first class mail this 1st day of May 2017.

/s/ *Richard A. Rosen*